



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 7, 2001

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 3573-TE / Mariner
DP Barcode: D271708
Case No: 068860

To: Adam Heyward, PM 34 / Portia Jenkins
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C) *Karen Hicks*
2/7/01

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: The Procter & Gamble Company

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% bv wt.</u>
Citric acid	4.5
<u>Other Ingredient(s):</u>	<u>95.5</u>
Total:	100.0%

BACKGROUND: The Procter & Gamble Company (P&G) is asking that AD/PSB reconsiders the acceptance of a Low-Volume Eye Test (LVET) conducted on their its product, "Mariner". P&G has been attempting to get AD/PSB to accept this study for a period of months. In 2000, they have met with several toxicologists and acute toxicity reviewers to discuss the details of this test method. OPP has agreed to accept this study when it is properly conducted and pertains to the product at hand.

In this presentation, P&G has a comparison of the formulations of "Mariner Bathroom Cleaner" with "Comet Bathroom Spray" and "Mr. Clean Bathroom Liquid". LVET results for Mariner and a discussion of the LVET results for Mariner. No actual study or report was included in this submission. The DER for this study was taken from a previous review of File Symbol 3573-TE.

RECOMMENDATIONS: PSB findings are:

The primary eye irritation study is acceptable.

The acute toxicity profile for File Symbol 3573-TE is currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	IV	acceptable
acute inhalation toxicity	IV	acceptable
primary eye irritation	IV	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	Nonsensitizer	acceptable

LABELING:

Date: 02/07/01 LABEL REVIEW SYSTEM

ID #: 003573-00072 Mariner

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS: (none required)

STATEMENT OF PRACTICAL TREATMENT (SOPT): (none required)

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 34
MRID No.: 451128-07

Reviewer: Ian Blackwell
Study Completion Date: 8/6/99
SLI Study No.: 3029.2218

Testing Laboratory: Springborn Laboratories, Inc.
Author(s): Kimberly L. Bonnette, M.S., LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: SS0623.01; EPA File Symbol 3573-TE; "clear, colorless liquid"

Dosage: 0.01 mL (This was a Low-Volume Eye Test)

Species: New Zealand White rabbits

Sex: 2 males + 1 female

Weight: 3.558-4.100 kg

Age: young adult

Source: Myrtle's Rabbitry

Summary:

1. Toxicity Category: IV
2. Classification: acceptable

Procedure (Deviations From §81-4):

❖ This study was conducted using the Low-Volume Eye Test method.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	0/3	0/3	---	---
Iritis	3/3	0/3	0/3	0/3	0/3	0/3	---	---
Conjunctivae								
Redness	2/3	0/3	0/3	0/3	0/3	0/3	---	---
Chemosis	0/3	0/3	0/3	0/3	0/3	0/3	---	---
Discharge	0/3	0/3	0/3	0/3	0/3	0/3	---	---

--- = no observations at this point